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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,538

03/11/2004

Srinka Ghosh

10030803-1

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22878 7590 04/01/2009

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

04/01/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,538	<b>Applicant(s)</b> GHOSH, SRINKA	
	<b>Examiner</b> LORI A. CLOW	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-25 is/are allowed.
- 6) ☒ Claim(s) 1-19, 26, and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

Applicants' response, filed 12 January 2009, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-27 are currently pending and under exam herein.

#### **Claim Objections**

Claim 27 is objected to because of the following informalities: It appears that claim 27 has a typographical error or is missing a word. Claim 27 reads as follows:

“A method carried out by an electronic computer under control of a computer program...computing...detecting by an electronic computer, the presence of features with convergence metrics larger than said threshold value **is** indicative of the presence of a background intensity gradient within said microarray data set”.

Perhaps the claim is meant to read as follows, or some other variation, to be grammatically correct:

“A method carried out by an electronic computer under control of a computer program...computing...detecting by an electronic computer the presence of features with convergence metrics larger than said threshold value **wherein the presence of features with convergence metrics larger that said threshold value is** indicative of the presence of a background intensity gradient within said microarray data set”.

Appropriate correction is required.

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**Claim Rejections - 35 USC § 101-Non-statutory Subject Matter**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, 26 and 27 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Parts of the instant rejection constitute a new grounds of rejection as necessitated by the recent decision in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

Claims 1, 12, 26, and 27 are drawn to a method carried out by an electronic computer under control of a computer program for detecting a background intensity gradient within a microarray data set.

As stated in MPEP 2106, section IV if the claims are found to cover a judicial exception then the claims will be evaluated for providing a practical application of the judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). This is in line with the recent decision in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

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As such, the claims must be further evaluated for providing the practical application. One way to do this is for the claim to produce a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case claims 1-10 and 12-18 include the step of "outputting by an electronic computer a numerical indication of the determined background intensity" or "outputting by an electronic computer a numerical indication of the characterized background intensity" which **does** provide a tangible result that is useful to one skilled in the art and thus provides a practical application. However, claims 26 and 27 fail to provide a result that provides a practical application. Mere "determining by an electronic computer that the microarray data set exhibits a background intensity" or "detecting by an electronic computer the presence of features" does not provide a tangible result that is useful to one skilled in the art. This portion of the rejection as applied to claims 26 and 27 could be overcome by amending the instant claims to recite a step of "outputting" or "providing an indication by determining" or "providing an indication by detecting". Applicant is reminded that any such amendment must have support in the Specification as originally filed.

In addition to the facts set forth above that state that a claim must provide a practical application, the claim **must also meet** the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008)). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not

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patentable; (2) while an abstract concept **may have a practical application**, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, the method claims are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not tied to any **particular apparatus or machine**" and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). It is appreciated that Applicant has attempted to overcome the rejection by amending the claims to recite "a method carried out by an electronic computer under control of a computer program" and amending the steps in the claims to recite the same. However, the recited "electronic computer" is not necessarily a specific machine for the implementation of said method steps and could be any such computer configured to make computational analyses. Therefore, the claims still do not include a tie to a specific machine. This portion of the rejection as it applies to claims 1-10, 12-18, 26, and 27 could be overcome by a claim amendment reciting "a method carried out by a suitably programmed computer for detecting a background intensity gradient within a microarray data set"... "computing by the suitably programmed computer convergence metrics"...determining by the suitably programmed computer", etc... The instant specification

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provides support for a suitably programmed computer, as the instant specification discloses program code for the instant method steps.

Finally, in addition to the above analysis regarding the said method claims, it is noted that claims 11 and 19 recite “a computer program that controls an electronic computer to carry out the method of claim 1 stored in a computer-readable medium”. A computer program stored on a computer-readable medium reads on carrier waves, which read on transitory propagating signals which are not proper patentable subject matter because they do not fit within any of the four statutory categories of invention (*In re Nuijten*, Federal. Circuit, 2006). The specification indicates, at page 11, that the data can be represented as electronic signals and also can be physical media. Therefore, the specification reads on both physical and non-physical embodiments of the computer readable media. This rejection could be overcome by stating on the record that by computer readable medium, Applicant’s intend only physical embodiments and not embodiments that read on carrier waves.

Claims 20-25 are statutory and are not rejected herein.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 27 recites, “the presence of features with convergence metrics larger than said threshold value”. There is insufficient antecedent basis in the claim for “said threshold value” as no threshold value was previously recited in the claim. Clarification is requested.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the relationship, in claim 27, between steps (1) drawn to computing convergence metrics for features within the microarray data set and step (2) drawn to detecting the presence of features with convergence metrics to indicate a background intensity gradient. Step (1) computes convergence metrics and when they are larger than a threshold value, somehow determines that the microarray data set exhibits a background intensity without any steps in which to "determine" the exhibition of a background intensity.

The instant specification discloses that:

"in general, the intensity associated with a pixel in the image of a microarray is the sum of: (1) a signal-intensity component produced, at a location of the surface of the microarray corresponding to the pixel, by bound target molecules; and (2) a background-intensity component produced by a wide variety of background-intensity-producing sources, including noise produced by electronic and optical components of a microarray scanner, general non-specific reflection of light from the surface of the microarray during scanning, or, in the case of radio-labeled target molecules, natural sources of background radiation, and various defects and contaminants on, and damage associated with, the surface of the microarray. A wide variety of different computational techniques are employed to determine the background-intensity components of pixel intensities and to subtract the background-intensity components from measured pixel intensities in order to recover the signal-intensity components.

Unfortunately, it may be difficult to precisely determine the background intensity components of pixels in an image of a microarray, particularly when the microarray contains contaminants and/or defects that produce background intensity gradients within the image of the microarray.



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For this reason, designers, manufacturers, and users of microarrays and microarray scanners continue to seek improved and computationally efficient methods for detecting defects and damage reflected in background intensity gradients in images of microarrays (page 5, lines 23-30 to page 6, lines 1-11)".

The specification further teaches that:

"the background intensity is expected to be relatively uniformly distributed within the image of a microarray, and have a variance and average magnitude characteristic for the type of microarray, experimental procedure, and microarray scanner used to scan the microarray. In processing microarray data, the background-intensity component is generally estimated, by any of various computational techniques, and subtracted from the measured intensity to produce an estimated signal intensity. However, in reality, the background intensity components associated with pixels in the image of a microarray may be quite non-uniformly distributed. Non-uniform distributions of background-pixel intensities across the image of a microarray may result from background intensity gradients within the image of a microarray" (page 13, lines 1-9).

The specification proposes that the instant invention provide an efficient method for determining features in a microarray in that:

"a convergence metric is computed for a feature by determining the size of a region surrounding the feature for which the difference between the mean and median pixel intensities is large. Features with computed metrics of large magnitudes are generally found in, or adjacent to, regions within the image of the microarray with steep background intensity gradients. The presence of features with computed metrics of large magnitudes may be used in one or more embodiments as an indication of the presence of background intensity gradients within the image of the microarray, and the patterns of distribution of such features within an array of features may be used to provide an indication of the location and directions of background intensity gradients within the image of the microarray (page 6, lines 16-27)".

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In order to perform the instant method of determining whether or not a microarray data set exhibits a background intensity gradient after computing a convergence metric it is essential that the presence of features that have large computed metrics are used to determine a background intensity gradient within the microarray. However, the instant claims are missing the computation step of actually using the metric in the determination of the background intensity gradient. Without such a step in the claims, essential elements for operation are omitted.

### **Conclusion**

Claims 20-25 are allowed. The prior art does not teach or fairly suggest a microarray data set analysis system comprising a process as is instantly claimed. Specifically, the prior art does not teach or fairly suggest the computation of convergence metrics for features within a microarray image to determine background intensity gradients.

Claims 1-19, 26, and 27 are rejected for the reasons set forth above.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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March 30, 2009

/Lori A. Clow, Ph.D./

Primary Patent Examiner, Art Unit 1631